

K062898

NOV 13 2006

510(k) Summary

Manufacturer: ms Company  
8600 Evergreen Boulevard  
Minneapolis, MN 55433  
763-786-1520 – Office  
763-783-5073

Submitted By: Small Bone Innovations  
James O' Connor  
505 Park Avenue, 14<sup>th</sup> Floor  
New York, NY 10022  
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212-428-1791 – Office  
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Proprietary Name: SBI Lateral rHead Implant

Classification name: Class II, 888.3170 - prosthesis, elbow, hemi-, radial, polymer

Common/Usual Name: Elbow joint radial (hemi-elbow) polymer prosthesis

Substantial Equivalence: Documentation is provided which demonstrated the SBI Lateral rHead Implant to be substantially equivalent to other legally marketed devices.

Device Description: The SBI Lateral Assembly rHead prosthesis consists of a cobalt chromium stem and head. The stem of the implant is coated with CPTi coating and is designed to be inserted into the shaft of the proximal radius. The head of the implant articulates with the capitellum. The implant is available in several sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

Intended Use: The Radial Head Implant is intended for replacement of the proximal end of the radius:

1. Replacement of the radial head for degenerative, post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and or proximal radio-ulnar joint with:
  - a. Joint destruction or subluxation visible on x-ray.
  - b. Resistance to conservative treatment.

2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.

Material:

ASTM F-1537 wrought cobalt chromium molybdenum alloy for surgical implants

ASTM F-1580 titanium powders for coating of surgical implants



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Small Bone Innovations  
% Mr. James O'Connor  
505 Park Avenue, 14<sup>th</sup> Floor  
New York, New York 10022

NOV 13 2006

Re: K062898

Trade/Device Name: SBI Lateral rHead Implant  
Regulation Number: 21 CFR 888.3170  
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis  
Regulatory Class: II  
Product Code: KWI  
Dated: September 15, 2006  
Received: September 27, 2006

Dear Mr. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

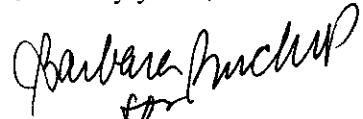
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Mr. James O'Connor

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K062898

Device Name: SBI Lateral rHead

### Indications For Use:

The SBI Lateral Assembly rHead is intended for replacement of the proximal end of the radius:

1. Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
  - a. Joint destruction or subluxation visible on x-ray
  - b. Resistance to conservative treatment
2. Primary replacement after fracture of the radial head
3. Symptomatic sequelae after radial head resection

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Barbara Bruchman  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices  
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